FORM PTO-1390 (Modified) (REV 11-2000) U.S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
RLL-159US	
U.S. APPLICATION NO (IF KNOWN, SEE 37 CFR	
HEREWITH 10/009230	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/IB00/00708	25 MAY 2000	25 MAY 1999

TITLE OF INVENTION

AMORPHOUS FORM OF FEXOFENADINE HYDROCHLORIDE

APPLICANT(S) FOR DO/EO/US

NARESH KUMAR, CHANDRAS HAS KHANDURI, MUKESH SHARMA

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U S C 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   - a ☐ is attached hereto (required only if not communicated by the International Bureau)
   - b. ☒ has been communicated by the International Bureau.
   - c ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))
   - a. ☐ is attached hereto.
   - b. ☐ has been previously submitted under 35 U S.C 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   - b ☐ have been communicated by the International Bureau.
   - c ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U S C 371(c)(3))
9. ☐ An oath or declaration of the inventor(s) (35 U S C 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S C 371 (c)(5))
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U S C 154(d)(4).
22. ☒ Certificate of Mailing by Express Mail
23. ☒ Other items or information

RETURN POST CARD

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/009230 HEREWITH	PCT/IB00/00708	RLL-159US

24. The following fees are submitted..

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO	$1040.00	
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO	$890.00	
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$740.00	
☒ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4)	$710.00	
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)	$100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =		$710.00
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).		$130.00

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	13 - 20 =	0	x $18.00	$0.00
Independent claims	2 - 3 =	0	x $84.00	$0.00
Multiple Dependent Claims **(check if applicable).**			☐	$0.00
TOTAL OF ABOVE CALCULATIONS =				$840.00
☐ Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				$0.00
SUBTOTAL =				$840.00
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +				$0.00
TOTAL NATIONAL FEE =				$840.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).** ☐				$0.00
TOTAL FEES ENCLOSED =				$840.00
			Amount to be: refunded	$
			charged	$

a. ☐ A check in the amount of _____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. **50-0912** in the amount of **$840.00** to cover the above fees A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No **50-0912** A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

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SIGNATURE

JAYADEEP R. DESHMUKH
NAME

34,507
REGISTRATION NUMBER

NOVEMBER 5, 2001
DATE

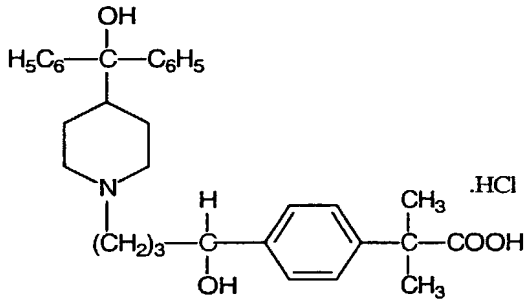
AMORPHOUS FORM OF FEXOFENADINE HYDROCHLORIDE

FIELD OF THE INVENTION

This invention relates to an amorphous form of fexofenadine hydrochloride, to a process for the preparation thereof, and to a composition containing it.

BACKGROUND OF THE INVENTION

Chemically, fexofenadine is 4-[4-[4-hdroxydiphenylmethyl)-1-piperidinyl]-hydroxybutyl]-α, α-dimethylbenzene acetic acid also known as terfenadine carboxylic acid metabolite having the Formula I.



Formula I

Fexofenadine hydrochloride (Terfenadine carboxylic acid hydrochloride) is an effective antihistamine which avoids adverse effects associated with the administration of terfenadine including abnormal heart rhythms in some

patients with liver disease or who also take the antifungal drug ketoconazole or the antibiotic erythromycin.

The pharmaceutical industry has, of late, conducted studies on polymorphism in drugs and the difference in the activity of different polymorphic forms of a given drug. By the term polymorphism we mean to include different physical forms, crystal forms, crystalline/liquid crystalline/non-crystalline (amorphous) forms. This has especially become very interesting after observing that many antibiotics, antibacterials tranquilizers etc, exhibit polymorphism and some/one of the polymorphic forms of a given drug exhibit superior bio-availability and consequently show much higher activity compared to other polymorphs. It has also been disclosed that the amorphous forms in a number of drugs exhibit different dissolution characteristics and in some cases different bioavailability patterns compared to the crystalline form [Konne T., Chem. Pharm. Bull. 38, 2003 (1990)]. For some therapeutic indications one bioavailability pattern may be favoured over another. Cefuroxime axetil is a good example of an amorphous form exhibiting higher bioavailability than the crystalline form. Sertraline, Frentizole, Sulphathiazole, Indomethacine, etc., are some of the important examples of pharmaceuticals which exhibit polymorphism. A number of patents have been granted pertaining to these new forms of old drugs. To cite a few, US Patent No. 5,248,699 discloses five polymorphic forms of sertraline hydrochloride while EP 014490 describes four polymorphic forms of Frentizole. EP 490648 and EP 022527 also deal with the subject of polymorphism in drugs.

PCT patent application WO 95/31437 discloses fexofenadine hydrochloride in various new crystalline forms designated Form I, Form II and Form IV and methods for their preparation.

SUMMARY OF THE INVENTION

The first object of the present invention is to provide fexofenadine hydrochloride in an amorphous form. The amorphous form of fexofenadine hydrochloride is prepared by an efficient process which uses conditions which are convenient to operate on a commercial scale and operationally safe.

The second object of the present invention is to provide a process for the preparation of fexofenadine hydrochloride in an amorphous form which comprises dissolving crystalline fexofenadine hydrochloride in a suitable solvent or dissolving fexofenadine base in a suitable solvent and adding a suitable solvent containing hydrogen chloride and recovering amorphous form of fexofenadine hydrochloride from the solution thereof by spray drying or freeze drying technique.

In yet another aspect of this invention, there is provided a pharmaceutical composition comprising fexofenadine hydrochloride in an amorphous form with one or more pharmaceutical carriers and/or excipients.

DETAILED DESCRIPTION OF THE INVENTION

In a preferred embodiment of the invention, fexofenadine hydrochloride is recovered from the solution in an amorphous form using a freeze drying

technique. The freeze dryer (Model : Virtis Genesis SQ Freeze – Dryer), which is used, operates on the principle of lyophilization, i.e., a process of stabilizing initially wet materials (aqueous solution or suspensions) by freezing them, then subliming the ice while simultaneously desorbing some of the bound moisture (primary drying). Following disappearance of the ice, desorption may be prolonged (secondary drying). This process is preferably conducted under vacuum.

In a more preferred embodiment of the invention, fexofenadine hydrochloride is recovered from the solution in an amorphous form using a spray drying technique. The Mini-Spray Dryer (Model : Buchi 190, Switzerland) which is used, operates on the principle of nozzle spraying in a parallel – flow, i.e., the sprayed product and the drying gas flow in the same direction. The drying gas can be air or inert gases such as nitrogen, argon and carbon dioxide. Nitrogen is preferred in this case.

The term "suitable solvent" means lower alkanol or combination of lower alkanol, ester, ketone, chlorinated solvent and mixture (s) thereof. Lower alkanol includes those primary, secondary and tertiary alcohols having from one to six carbon atoms. Suitable lower alkanol solvents include methanol, ethanol, n-propanol, isopropanol, n-butanol, isobutanol, amyl alcohol and t-butanol. The term ketone or ester includes solvents having from one to ten carbon atoms such as acetone, methyl ethyl ketone, 2-butanone, 4-methylpentan-2-one, ethyl acetate or n-butylacetate. The suitable chlorinated

solvents include dichloromethane, chloroform or carbon tetrachloride. Mixture of these solvents are also contemplated.

Amorphous fexofenadine hydrochloride prepared according to the process of the present invention may be characterized by its infra-red spectrum in KBr disc (Figure 1) and by its X-ray powder diffraction pattern (Figure 2). The infra red spectrum in KBr (Figure 1) obtained for the samples prepared by the process of the present invention is different than infra red spectrum in KBr for crystalline form (Figure 3) of fexofenadine hydrochloride obtained per WO patent application (WO 95/31437). X-ray powder diffraction patterns gave a plain halo (Figure 2) and show no peaks which are characteristic of a crystalline fexofenadine hydrochloride (Figure 4) thus demonstrating the amorphous nature of the product.

The present invention is illustrated by the following examples which are not intended to limit the effective scope of the claims.

Preparation of amorphous fexofenadine hydrochloride by Spray Drying using crystalline fexofenadine hydrochloride

EXAMPLE 1

Fexofenadine hydrochloride crystalline (124g, 0.231 moles) was dissolved in methanol (300ml) at 25-30ºC. The clear solution so obtained was subjected to spray drying in a Mini-Spray Dryer (Buchi Model 190) and fexofenadine hydrochloride in an amorphous form was isolated (114g).

X-ray powder diffraction pattern (Figure 2) shows a plain halo thus demonstrating the amorphous nature of the product. Infrared spectrum in KBr (Figure 1) is different than the one obtained for crystalline form of fexofenadine hydrochloride (Figure 3).

EXAMPLE 2

The process of Example 1 was repeated with fexofenadine hydrochloride (10g, 0.0186moles) using ethylacetate (20ml) and methanol (20ml) instead of methanol to give amorphous fexofenadine hydrochloride (9.2g). IR (KBr) spectrum and x-ray crystallography confirmed that the material was amorphous in nature.

EXAMPLE 3

The process of Example 1 was repeated with fexofenadine hydrochloride (10g, 0.0186 moles) using acetone (20ml) and methanol (20ml) instead of methanol to give amorphous fexofenadine hydrochloride (8.9g). IR (KBr) spectrum and x-ray crystallography examination confirmed the amorphous nature of the product.

Preparation of amorphous fexofenadine hydrochloride by spray drying using fexofenadine base.

EXAMPLE 4

Fexofenadine (15gm, 0.0299 moles) was suspended in methanol (60 ml) and to it was added isopropanol containing equivalent molar hydrogen

chloride to get a clear solution. The clear solution was subjected to spray drying in a mini spray dryer (Buchi Model 190) and fexofenadine hydrochloride in an amorphous form was isolated (14.9g). IR (KBr) and x-ray crystallography revealed that the product was amorphous.

EXAMPLE 5

The process of Example 4 was repeated with fexofenadine (10g, 0.0199 moles) using methanol (40ml) and to it was added methanol containing equimolar hydrogen chloride to give amorphous fexofenadine hydrochloride (9.5g). IR (KBr) spectrum and x-ray crystallography examination confirmed the amorphous nature of the product.

WE CLAIM :

1. Fexofenadine hydrochloride in an amorphous form.

2. A pharmaceutical composition containing a therapeutically effective amount of the amorphous form of claim 1 together with one or more pharmaceutical carriers or excipients.

3. A process for the preparation of fexofenadine hydrochloride in an amorphous form which comprises dissolving crystalline fexofenadine hydrochloride in a suitable solvent or dissolving fexofenadine base in a suitable solvent and adding a suitable solvent containing hydrogen chloride and recovering fexofenadine hydrochloride from said solution by spray drying or freeze drying technique.

4. The process of claim 3, wherein suitable solvent is selected from the group consisting of lower alkanol, ester, ketone, chlorinated solvent and mixtures thereof.

5. The process of claim 4, wherein lower alkanol includes primary, secondary and tertiary alcohols having from one to six carbon atoms.

6. The process of claim 5, wherein said lower alkanol is selected from the group consisting of methanol, ethanol, n-propanol, isopropanol or n-butanol and mixtures thereof.

7. The process of claim 6, wherein the solvent is methanol, ethanol or isopropanol.

8. The process of claim 4, wherein the ester solvent is selected from ethyl acetate or n-butyl acetate.

9. The process of claim 4, wherein the ketone solvent is acetone, methylethyl ketone, 2-butanone, 4-methylpentan-2-one.

10. The process of claim 4, wherein the chlorinated solvent is chloroform, dichloromethane or carbontetrachloride.

11. The process of claim 3, wherein fexofenadine hydrochloride in an amorphous form is isolated from said solution by spray drying.

12. The process of claim 3, wherein the spray drying is effected in the presence of an inert gas.

13. The process of claim 3, wherein fexofenadine hydrochloride in an amorphous form is isolated from said solution by freeze drying.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
30 November 2000 (30.11.2000)

PCT

(10) International Publication Number
WO 00/71124 A1

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(30) Priority Data:
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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*
— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 00/71124 A1

(54) Title: AMORPHOUS FORM OF FEXOFENADINE HYDROCHLORIDE

(57) Abstract: This invention relates to an amorphous form of fexofenadine hydrochloride, to a process for the preparation thereof, and to a composition containing it.

FIG. 1

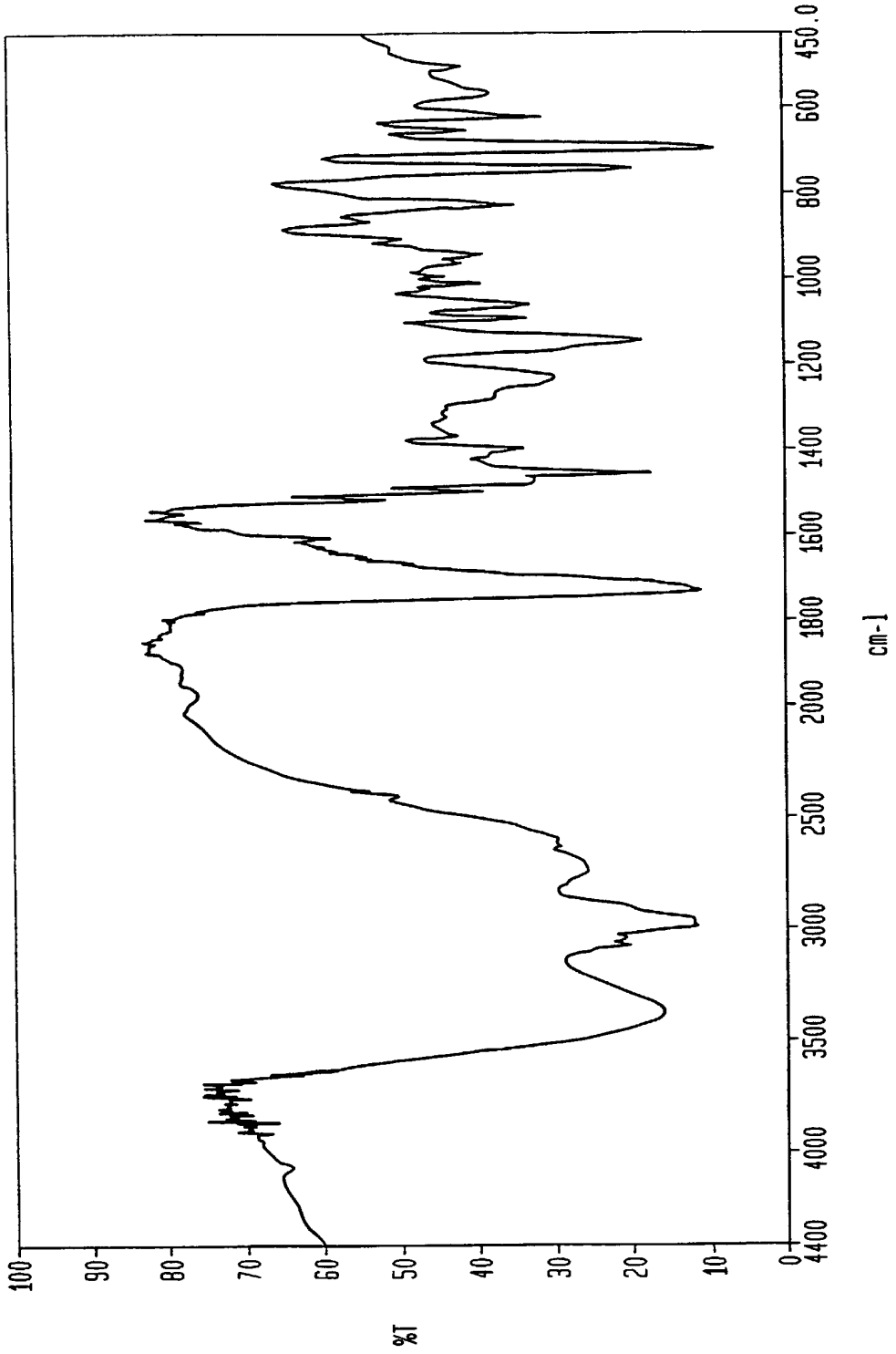
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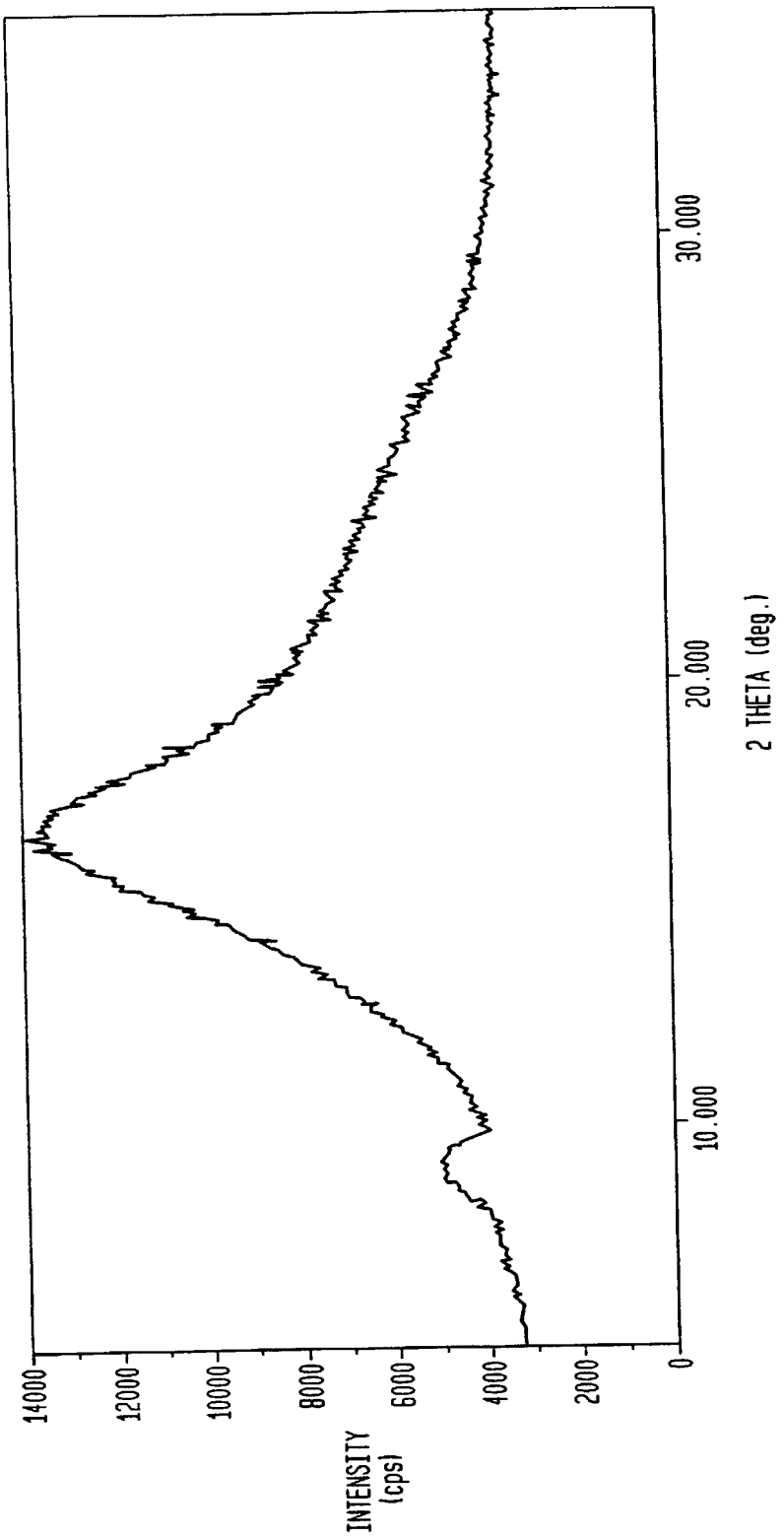
FIG. 2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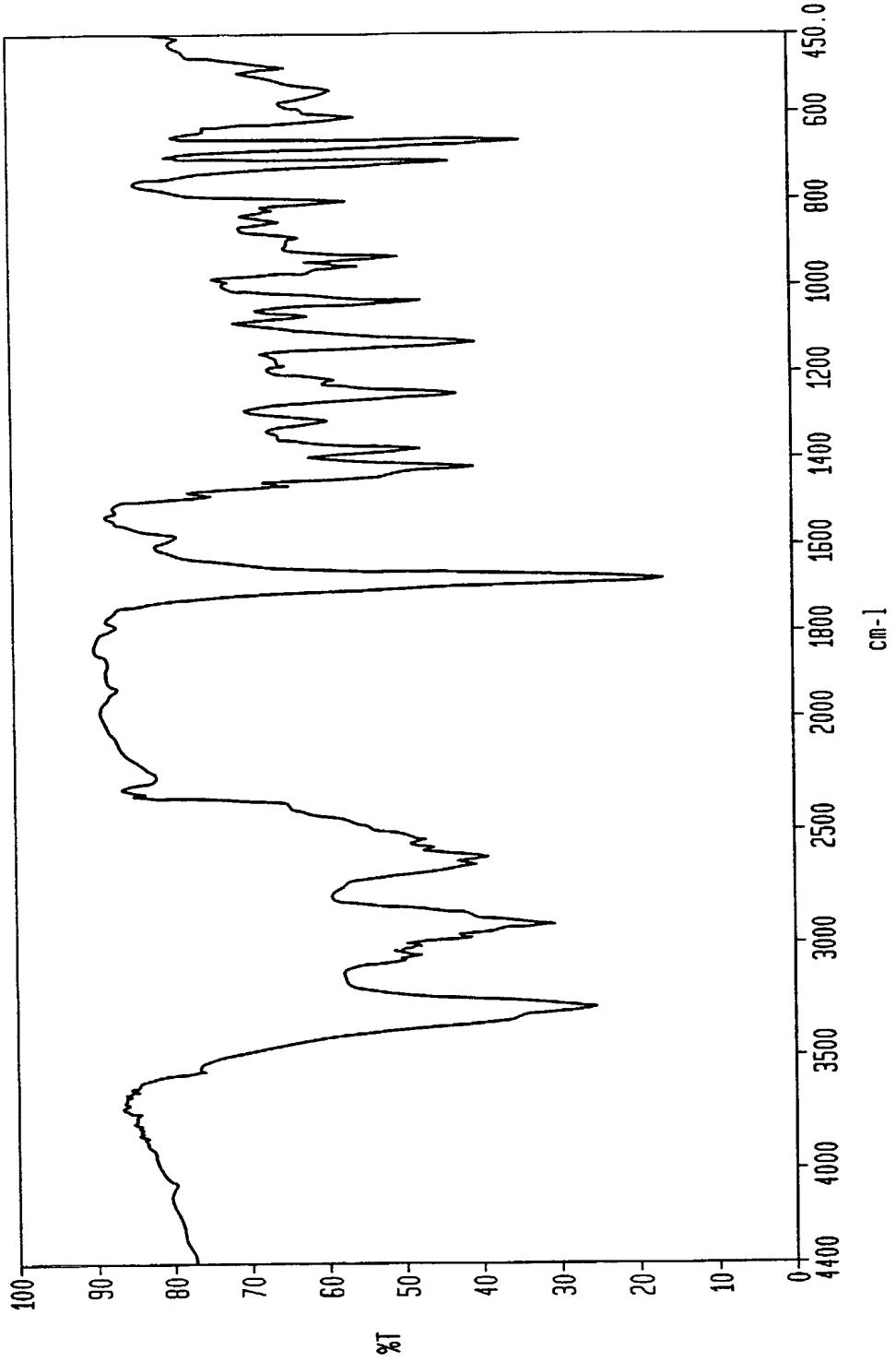
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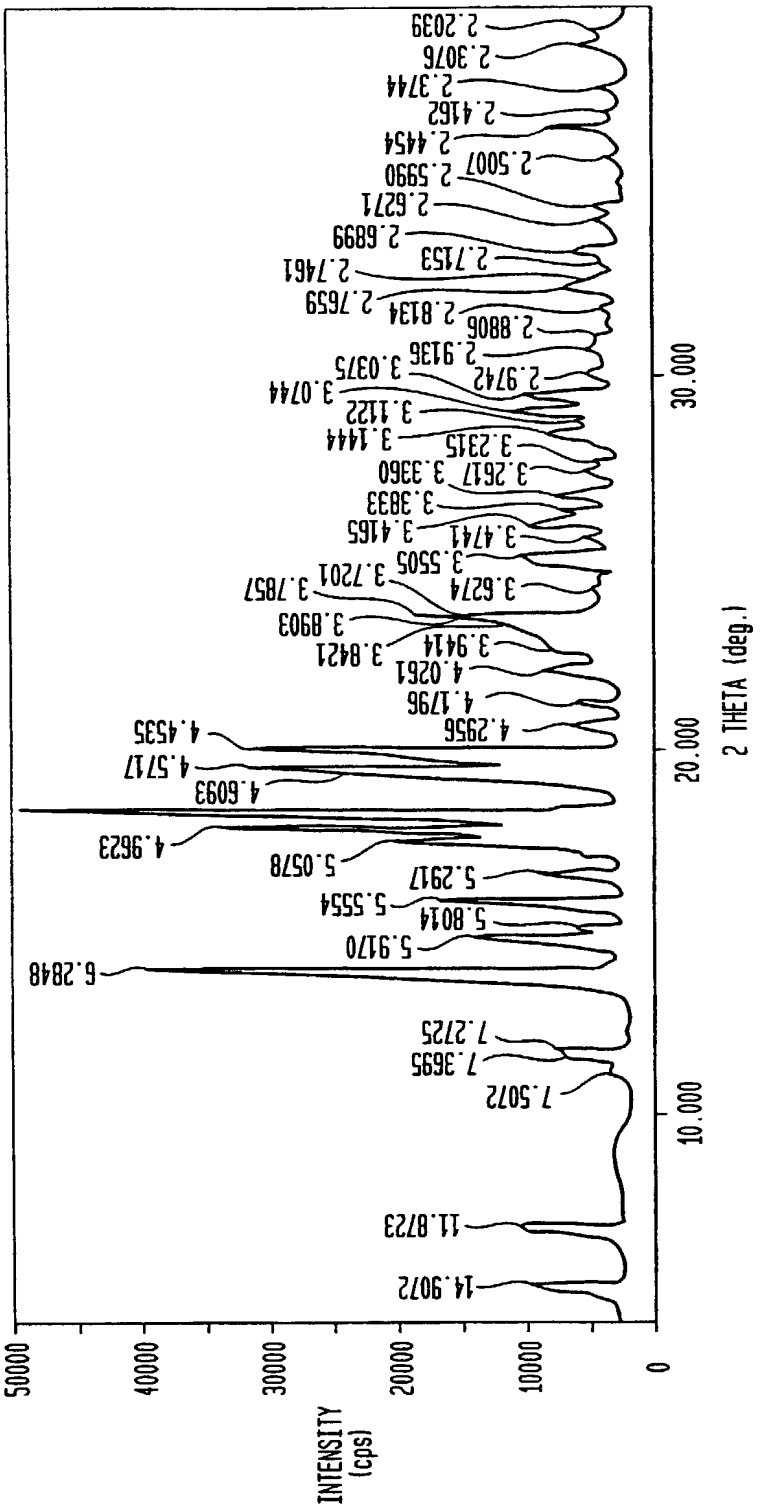
FIG. 4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Docket No.
RLL-159US

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

AMORPHOUS FORM OF FEXOFENADINE HYDROCHLORIDE

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on **May 25, 2000** as United States Application No. or PCT International Application Number **PCT/IB00/00708**

and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
776/Del/99	**India**	**25 May 1999**	☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1 56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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Ranbaxy Laboratories Limited
600 College Road East, Suite 2100
Princeton, New Jersey 08540

Direct Telephone Calls to: *(name and telephone number)*
Jayadeep R. Deshmukh, Esq. 609-720-5608

Full name of sole or first inventor **Naresh KUMAR**	
Sole or first inventor's signature Naresh Kumar	Date 28/04/02
Residence **Gurgaon, Haryana, India**	
Citizenship **India**	
Post Office Address **U-27/7, Phase-III, DLF Qutab Enclave, Gurgaon, Haryana 122 001 India**	

Full name of second inventor, if any **Chandras Has KHANDURI**	
Second inventor's signature	Date 18/04/02
Residence **Gurgaon, Haryana, India**	
Citizenship **India**	
Post Office Address **House No. 1952, Block - D, Palam Vihar, Gurgaon, Haryana 122 001 India**	

3-10

Full name of third inventor, if any **Mukesh SHARMA**
Third inventor's signature Date 18/04/2002
Residence **Gurgaon, Haryana, India**
Citizenship **India**
Post Office Address **House No. 1952, Block - D, Palam Vihar, Gurgaon, Haryana 122 001 India**

Full name of fourth inventor, if any
Fourth inventor's signature Date
Residence
Citizenship
Post Office Address

Full name of fifth inventor, if any
Fifth inventor's signature Date
Residence
Citizenship
Post Office Address

Full name of sixth inventor, if any
Sixth inventor's signature Date
Residence
Citizenship
Post Office Address